IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SMITH KLINE & FRENCH LABORATORIES LIMITED and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,	)	
Plaintiffs,	)	Civil Action No. 05-197-GMS
v.	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

JOINT STATUS REPORT

Plaintiffs Smith Kline & French Laboratories, Ltd., and SmithKline Beecham Corporation, doing business as GlaxoSmithKline, (hereinafter collectively "GSK") and Defendant Teva Pharmaceuticals USA, Inc. (hereinafter "Teva USA") submit this Joint Report in preparation for the Status and Scheduling Conference before this Court set for July 28, 2005, at 9:00 a.m., pursuant to Rule 16 of the Federal Rules of Civil Procedure and Local Rule 16.2(b).

1. **Jurisdiction and Service.** The parties agree that the Court has subject matter jurisdiction over this action and that the Court has personal jurisdiction over both GSK and Teva USA. At the present time, GSK and Teva USA believe that all necessary parties have been served and have appeared. Both GSK and Teva USA, however, reserve their rights to join additional parties within the time limit agreed to in section 7 of this report.

2. **Substance of the Action.** This is a patent infringement action relating to an Abbreviated New Drug Application ("ANDA") filed by Teva USA with the United States Food and Drug Administration ("FDA") for approval to market a generic version of GSK's Requip®

drug product. This action arises under the patent laws of the United States, 35 U.S.C. § 100, et seq.

GSK alleges that Teva USA has infringed United States Patent Nos. 4,452,808 ("the '808 patent") and 4,824,860 ("the '860 patent") by submitting ANDA No. 77-460 and related amendments ("the Teva USA ANDA") to the FDA. GSK also alleges that Teva USA's commercial manufacture, use, offer to sell, sale, or importation of the products that are the subject of the Teva USA ANDA prior to the expiration of the '808 and '860 patents, or its inducement of or contribution to such conduct, would further infringe the patents at issue. GSK further alleges that Teva USA's infringement of the '808 and '860 patents is willful. Teva USA denies that the filing of the Teva USA ANDA infringed any valid claim of the '808 and '860 patents. Teva USA also denies that the manufacture, use, offering for sale, sale, or importation of its proposed ropinirole hydrochloride products that are the subject of the Teva USA ANDA would infringe any valid claim of the '808 or '860 patents. Teva USA further denies that the filing of the Teva USA ANDA can or does form the basis of a finding of willful infringement.

Teva USA has raised the defenses of invalidity and non-infringement with respect to the '808 and '860 patents and has also filed counterclaims against GSK seeking declaratory judgment that the '808 and '860 patents are invalid and that neither the filing of the Teva USA ANDA nor the manufacture, use, offer to sell, sale, and/or importation into the United States of the products that are the subject of the Teva USA ANDA will infringe any valid claim of the '808 or '860 patents. GSK denies that Teva USA is entitled to any relief whatsoever, either as contained in Teva USA's Answer and Counterclaims or otherwise.

3. **Identification of Issues.** The issues in dispute are: (a) the validity of the '808 patent; (b) the validity of the '860 patent; (c) whether the filing of the Teva USA ANDA and/or

the manufacture, use, offer to sell, sale, and/or importation into the United States of the products that are the subject of the Teva USA ANDA has infringed, infringes, or will infringe any valid claim of the '808 patent; (d) whether the filing of the Teva USA ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of the products that are the subject of the Teva USA ANDA has infringed, infringes, or will infringe any valid claim of the '860 patent; and (e) whether infringement of the '808 and/or '860 patent (if found) was or is willful.

4. **Narrowing of Issues.** The parties have not identified any opportunities for narrowing the issues at this time but believe that there may be an opportunity at an early stage of this litigation to resolve the issues of infringement and/or willful infringement through briefing and/or stipulation. Teva USA believes that early identification of asserted claims would allow for the further narrowing of issues concerning infringement.

5. **Relief.** GSK seeks: (a) a declaration that the '808 and '860 patents are valid and enforceable; (b) a declaration that a claim or claims of the '808 and '860 patents are infringed by the manufacture, use, sale, offer for sale or importation of the products that are the subject of the Teva USA ANDA, that Teva USA's submission of the Teva USA ANDA is an act of infringement of the '808 and '860 patents, that Teva USA's making, using, offering to sell, selling, or importing the products that are the subject of the Teva USA ANDA, and its inducement of such conduct by others, will infringe the '808 and '860 patents, and that Teva USA's infringement is willful; (c) an Order providing that the effective date of any approval of the Teva USA ANDA shall be a date which is not earlier than the expiration of both the '808 patent and the '860 patent; (d) an Order permanently enjoining Teva USA and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, using,

offering to sell, selling, or importing the products that are the subject of the Teva USA ANDA and from inducing such conduct by others, until after expiration of both the '808 patent and the '860 patent; (e) reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by GSK in this action; and (f) such further and other relief as the Court deems proper and just. GSK is not seeking damages at this time but reserves the right to pursue damages or other monetary relief (including but not limited to treble damages and prejudgment interest).

Teva USA seeks: (a) a declaration that the filing of the Teva USA ANDA did not infringe any valid claims of the '808 and '860 patents; (b) a declaration that the manufacture, use, offer to sell, sale, and/or importation into the United States of the products that are the subject of the Teva USA ANDA will not infringe any valid claims of the '808 and '860 patents; (c) a declaration that the '808 patent is invalid; (d) a declaration that the '860 patent is invalid; (e) that Teva be awarded costs in this action; (f) that Teva be awarded attorneys' fees pursuant to 35 U.S.C. § 285; and (g) that Teva be awarded such other and further relief as the Court may deem just and proper. Teva is not seeking damages at this time but reserves the right to pursue damages or other monetary relief (including but not limited to treble damages and prejudgment interest).

6. **Amendment of Pleadings.** The parties propose that amendment of pleadings without leave of court must occur by November 4, 2005.

7. **Joinder of Parties.** The parties propose that joinder of all parties must occur by November 4, 2005.

8. **Discovery.** With the exception of the deadlines for the exchange of initial disclosures, motions to amend the pleadings, motions to join additional parties, and notice of reliance on advice of counsel as a defense to willful infringement, production of opinions of

counsel, and production of all related materials, the parties were unable to agree on a discovery schedule and hereby submit the following competing proposals:

Event	GSK Proposal	Teva USA Proposal
Fact Discovery		
Exchange of Initial Disclosures	August 5, 2005	August 5, 2005
Motion to Amend Pleadings	November 4, 2005	November 4, 2005
Motion to Join Additional Parties	November 4, 2005	November 4, 2005
Notice of Reliance on Advice of Counsel as a Defense to Willful Infringement, Production of Opinions of Counsel, and Production of all Related Materials	November 28, 2005	November 28, 2005
Completion of Fact Discovery	July 28, 2006	March 10, 2006
Markman Proceedings		
Exchange of claim terms to be construed and proposed constructions	March 3, 2006	February 3, 2006
Deadline for parties to meet and confer regarding narrowing and reducing the number of claim construction issues	March 10, 2006	February 10, 2006
Submission of Joint Claim Construction Chart	March 24, 2006	February 24, 2006
Markman Briefs	Opening: March 31, 2006 Response: April 14, 2006	Opening: March 3, 2006 Response: March 17, 2006
Markman Hearing	May 12, 2006	March 24, 2006
Expert Discovery		
Opening Expert Reports (burden of proof)	September 8, 2006	March 31, 2006
Answering Expert Reports	October 13, 2006	April 21, 2006
Reply Expert Reports	November 3, 2006	April 28, 2006
Completion of Expert Discovery	November 30, 2006	May 19, 2006
Dispositive Motions		
Letter Briefs Seeking Permission	Opening: November 29, 2006 Response: December 6, 2006 Reply: December 8, 2006	Opening: May 26, 2006 Response: June 2, 2006 Reply: June 6, 2006
Submission of Joint Agenda Identifying Daubert Issues	December 8, 2006	June 23, 2006
Hearing Concerning Permission to File Summary Judgment Motions	December 15, 2006, 10:00 a.m. by telephone	June 30, 2006
Hearing to Discuss Daubert Issues	December 15, 2006, 10:00 a.m. by telephone	June 30, 2006

Event	GSK Proposal	Teva USA Proposal
Summary Judgment Briefing (if permitted)	Opening: January 12, 2006 Response: February 1, 2007 Reply: February 11, 2007	Opening: July 21, 2006 Response: August 11, 2006 Reply: September 1, 2006
Summary Judgment Hearing	At Court's Discretion	At Court's Discretion
Trial Phase		
Motions in Limine	Opening: March 7, 2007 Response: March 14, 2007 Reply: March 19, 2007	Opening: September 13, 2006 Response: September 20, 2006 Reply: September 25, 2006
Plaintiff's Draft re Joint Proposed Pretrial Order	February 26, 2007	September 1, 2006
Submission of Joint Proposed Pretrial Order	March 21, 2007	September 29, 2006
Pretrial Conference	March 28, 2007 10:00 a.m.	October 4, 2006
Trial	April 23, 2007	October 10, 2006

The parties propose that they adhere to the limitations on requests for production, interrogatories, and requests for admission set forth in the Local Rules, except as follows: each side is presumptively limited to taking 10 depositions, excluding expert depositions. A party must obtain a stipulation of the opposing party or leave of court if a proposed deposition would result in more than 10 fact depositions being taken by that party. The parties further agree that, for purposes of applying this limitation, a deposition of a corporate representative noticed pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure shall count as one deposition, even if more than one individual is named as a corporate witness. The parties also agree on the need for a Protective Order specifying terms and conditions for the disclosure of confidential information and will attempt to reach an agreement on a proposed form of order.

Teva USA believes that this case is less complex than the typical patent dispute. Teva USA believes that infringement issues are likely to be comparatively narrow, particularly if plaintiffs identify the claims they are asserting early in the discovery process. Teva USA disputes whether plaintiffs can properly maintain a claim for willful infringement in the case. See *Glaxo Group Ltd. v. Apotex , Inc.*, 376 F.3d 1339, 1349 (Fed. Cir. 2004) ("[T]he mere filing of an ANDA cannot constitute grounds for a willful infringement determination . . . .") Teva USA further believes that early resolution of this question has the possibility of narrowing document production and depositions. Finally, Teva USA also contends that, as an ANDA case, damages will not be an issue in discovery or trial.

GSK disagrees with Teva USA's assertion that this case is less complex than the typical patent dispute. GSK believes it would be premature at this stage, when discovery has not yet commenced, to conclude that issues concerning infringement and willful infringement can be easily resolved and that damages will not be an issue. Furthermore, GSK contends that the *Apotex, Inc.* case cited by Teva USA above is distinguishable from this case because, among other things, it did not involve the filing of a Paragraph IV certification. Moreover, *Apotex, Inc.* does not foreclose the possibility of willful infringement in an ANDA case where the facts so warrant, and GSK is entitled to pursue discovery in an effort to prove that such facts are present here. Furthermore, it is GSK's view that the discovery process in this case is likely to be time-consuming and burdensome, given the size and scope of both parties' global operations, the likely need for international discovery, and the potentially expansive time period at issue. GSK also believes that a substantial period of time will be required for expert discovery in this case in light of Teva USA's challenge to the validity of GSK's patents.

9. **Estimated Trial Length.** The parties estimate 10 days for this action to be tried. At the present time, the parties do not have any issues that they believe should be bifurcated for trial. At the present time, the parties have not identified any specific means of reducing the length of trial or expediting the presentation of evidence.

10. **Jury Trial.** The parties have not demanded a jury trial at this time but reserve the right to do so if circumstances change.

11. **Settlement.** During the Rule 26(f) teleconference, counsel for the parties raised the issue of settlement and determined that settlement discussions would not be productive at this time. The parties do not believe the referral to the Magistrate for mediation or any other ADR mechanism is appropriate at this time.

12. **Other Matters.** There are no other matters relating to the just, speedy, and inexpensive determination of this action that counsel for the parties wish to confer about or raise with the Court at this time.

13. **Confirmation of Rule 26(f) Teleconference.** Counsel for GSK and Teva USA have conferred regarding each of the topics listed above. Should the Court have any questions regarding the information set forth above, counsel for both parties are prepared to provide the additional information needed to address the Court's concerns.

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